



A RADICAL WAY TO BLOCK TESTOSTERONE... STARTING DAY 1

USE FIRMAGON FIRST

52% of patients attained castrate levels of testosterone (≤ 50 ng/dL) on Day 1 with FIRMAGON® (degarelix for injection) (n=207) vs 0% of patients on leuprolide (n=201) (secondary endpoint, noninferiority study). At 1 year (primary endpoint), 97.2% of patients on FIRMAGON and 96.4% of patients on leuprolide achieved castrate levels.^{1,2}

FIRMAGON is a GnRH receptor antagonist indicated for treatment of patients with advanced prostate cancer.

Important Safety Information. FIRMAGON is contraindicated in patients with a known hypersensitivity to degarelix or to any of the product components and in women who are or may become pregnant. FIRMAGON can cause fetal harm when administered to a pregnant woman.



USE FIRMAGON® (degarelix for injection) FIRST: IN 3 PATIENT TYPES

FIRMAGON is a GnRH receptor antagonist indicated for treatment of patients with advanced prostate cancer.





USE FIRMAGON® (degarelix for injection) FIRST: IN 3 PATIENT TYPES



JOE H.
AGE 57
LIBRARIAN

Planning to start hormone therapy prior to receiving radiation therapy in the coming months, and wants a rapid reduction in testosterone levels



THOMAS W.
AGE 62
TECHNICIAN

Considering the addition of a short-term antiandrogen with an LHRH agonist to avoid testosterone surges



GREGORY B.
AGE 57
MECHANICAL ENGINEER

Considering hormone therapy due to rising PSA levels, even after curative attempt

These patient profiles are representative of typical patients with locally advanced prostate cancer. These are not actual patients.

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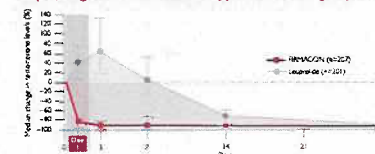
Important Safety Information. Long-term androgen deprivation therapy (ADT) prolongs the QT interval. Physicians should consider whether the benefits of ADT outweigh the potential risks in patients with congenital long QT syndrome, electrolyte abnormalities, or congestive heart failure and in patients taking Class IA or Class III antiarrhythmic medications.



FIRMAGON® (degarelix for injection) PROVIDES SURGE-FREE TESTOSTERONE SUPPRESSION STARTING DAY 1^{1,2}

- 52% of patients attained castrate levels of testosterone (≤ 50 ng/dL) on Day 1 with FIRMAGON (n=207) vs 0% of patients on leuprolide (n=201) (secondary endpoint, noninferiority study). At 1 year (primary endpoint), 97.2% of patients on FIRMAGON and 96.4% of patients on leuprolide achieved castrate levels¹
- 52% of patients achieved castrate levels by Day 1¹
- 96% of patients achieved castrate levels by Day 3¹

Rapid, surge-free testosterone suppression starting Day 1^{1-3*}



*Castrate levels are defined as ≤ 50 ng/dL of testosterone.

¹Leuprolide has been shown to cause an immediate testosterone surge of 50% or more upon dose initiation⁴

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Important Safety Information. Diagnostic test results of pituitary gonadotropic and gonadal functions conducted during and after FIRMAGON may be affected. The therapeutic effect of FIRMAGON should be periodically monitored by measuring serum concentrations of PSA; if PSA increases, serum concentrations of testosterone should be measured.



FIRST



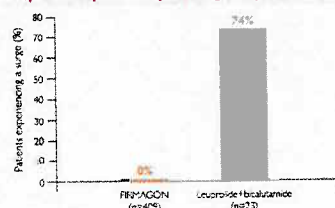
FIRST



IN A PHASE 3 CLINICAL TRIAL,
0% OF PATIENTS RECEIVING
FIRMAGON
EXPERIENCED
TESTOSTERONE
SURGES²

■ 74% of patients (n=23) who received bicalutamide in combination with leuprolide still experienced testosterone surges within the first 2 weeks, as shown in the FIRMAGON phase 3 clinical trial³

Proportion of patients experiencing a surge over 2 weeks³



*A testosterone surge was defined as a $\geq 15\%$ increase from baseline on any 2 days during the first 2 weeks of the study. About half of the patients receiving leuprolide who did not qualify for the prespecified definition of a surge did experience a $\geq 15\%$ increase in testosterone levels from baseline on 1 day during the first 2 weeks.³

³These data were obtained from a retrospective analysis.

²2.4% of patients had 1 testosterone value above 10 ng/dL from Day 28 through Day 364; 1.9% of patients had insufficient response to treatment (defined as 1 testosterone value above 100 ng/dL or 2 consecutive values above 50 ng/dL).

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Important Safety Information. The most common adverse reactions ($\geq 10\%$) during FIRMAGON therapy included injection site reactions (eg, pain, erythema, swelling or induration), hot flashes, increased weight, fatigue, and increases in serum levels of transaminases and gamma-glutamyltransferase. The majority of adverse reactions were Grade 1 or 2; 1% or less were Grade 3/4. Injection site reactions were mostly transient, of mild to moderate intensity, occurred primarily with the starting dose and led to few discontinuations ($<1\%$).

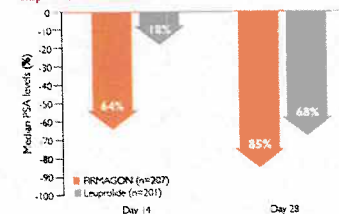


FIRMAGON
REDUCES PSA LEVELS
BY MORE THAN
60%
IN JUST 2 WEEKS²

Provides rapid and sustained reduction in PSA²

- In 2 weeks, FIRMAGON reduced PSA levels by 64%²
- Patients treated with LHRH agonists experienced an 18% overall reduction in 2 weeks²

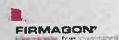
Rapid PSA reduction²



These PSA results should be interpreted with caution because of the heterogeneity of the patient population studied; no evidence has shown that the rapidity of PSA decline is related to a clinical benefit.

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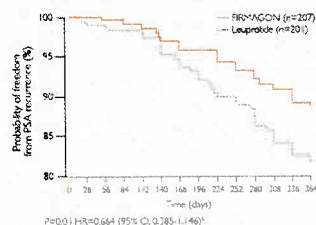


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FIRMAGON[®] PROVIDES IMPROVED LONG-TERM REDUCTION IN THE RISK OF PSA RECURRENCE VS AN LHRH AGONIST¹

- FIRMAGON[®] demonstrated a 34% greater reduction in the risk of PSA recurrence at 1 year vs an LHRH agonist¹
- FIRMAGON[®] patients were less likely to experience a PSA recurrence in 1 year²



These PSA results should be interpreted with caution because of the heterogeneity of the patient population studied; no evidence has shown that the rapidity of PSA decline is related to a clinical benefit.

¹PSA progression-free survival time to event was defined as the number of days from first dosing to the first of PSA recurrence (defined as 2 consecutive increases in PSA of 50% compared with nadir and ≥ 5 ng/mL on 2 consecutive measurements at least 2 weeks apart) or death; data include 9 deaths in the leuprolide group and 3 deaths in the FIRMAGON group.

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FIRMAGON[®] (degarelix for injection) INDICATION AND IMPORTANT SAFETY INFORMATION

FIRMAGON is a GnRH receptor antagonist indicated for treatment of patients with advanced prostate cancer.

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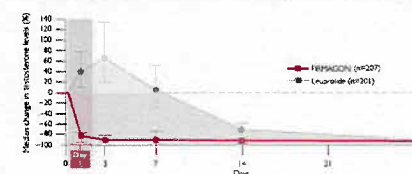
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FIRMAGON® (degarelix for injection) PROVIDES SURGE-FREE TESTOSTERONE SUPPRESSION STARTING DAY 1

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Rapid, surge-free testosterone suppression starting Day 1



Results were obtained from a pivotal, randomized, open-label, parallel-group, noninferiority phase 3 clinical trial. The primary endpoint of the study was testosterone suppression (≤ 50 ng/dL) for 1 year in patients receiving FIRMAGON or leuprolide.

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REFERENCES

1. FIRMAGON [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc; 2009.
2. Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of degarelix: a 12-month comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. *BJU Int*. 2008;102:1531-1538.
3. Data on file, Ferring Pharmaceuticals Inc.
4. LUPRON DEPOT® 7.5 mg [package insert]. North Chicago, IL: Abbott Laboratories; 2008.
5. Tombal B, Miller K, Boccon-Gibod L, et al. Additional analysis of the secondary end point of biochemical recurrence rate in a phase 3 trial (CS21) comparing degarelix 80 mg versus leuprolide in prostate cancer patients segmented by baseline characteristics. *Eur Urol*. 2010;57:836-842.

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FIRMAGON
degarelix for injection

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